Enrich
INTERNATIONAL

November 22, 1999

Food and Drug Administration
Attn: Peter J. Vardon
Dockets Management Branch (HFA-305)
Docket No. 96N-0417
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Impact of CGMP's on Small Businesses

Dear Mr. Vardon:

Enrich International, Inc. is pleased to respond to your invitation published in the Federal Register on September 3, 1999, pg. 48336, to submit information on how the industry proposed Current Good Manufacturing Processes ("CGMP's") would economically impact small businesses. Under your definition, Enrich International is presently a small business with 450 employees. It manufactures and distributes dietary supplements and skin care products internationally and in the United States. Embraced in all of the manufacturing processes Enrich International is a philosophy of safety and quality.

Background

Enrich International follows good manufacturing practices ("GMP's") in all its manufacturing processes. Its manufacturing facility is certified as GMP compliant by the Therapeutic Goods Agency (TGA), the Australian government health agency with responsibilities similar to those of the FDA. The company is also certified by the Health Protection Branch (HPB) of Canada's Health Ministry. The GMP's required by these agencies meet or exceed the CGMP's.

Economic Impact Discussion

Should the FDA require that all segments of the dietary supplement industry comply with the CGMP's, Enrich International will suffer a significant economic impact. However, by limiting the CGMP's to the proper segments of the industry, Enrich International and other end product manufacturers would suffer little economic impact.

The substance of the CGMP's clearly apply to those manufacturers that manufacture, package, and label the final products in the form that will be purchased and consumed by the public.

However, under Definition (k) in the CGMP's: "'manufacture' or 'manufacturing' *includes all operations associated with the production* of dietary products, including packaging and labeling operation, testing, and quality control of a dietary ingredient or dietary supplement" (emphasis

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added). Thus, by its definition, the CGMP's as proposed extend to all segments of the manufacturing chain. Should segments such as farmers and some brokers be required to follow certain provisions of the CGMP's, their costs would rise unnecessarily and significantly. These costs would be passed on to the end product manufacturers and ultimately to the consumers.

Those provisions of the CGMP that would unnecessarily raise the costs of production are in the categories *Quality Control and Laboratory Operations* and *Production and Process Controls.* Specifically, the requirements to have a quality control unit, adequate laboratory facilities, written quality control procedures, laboratory records, master production and control records, batch production and control records, and raw material testing would be unnecessarily burdensome. Costs would include not only the expense of additional personnel to staff the duties raised by the requirements, but also significant capital outlays to construct or redesign facilities. Such costs would impose an unnecessary burden on a farmer who supplies, for example, raw alfalfa harvested from his field and on a broker who merely wholesales the alfalfa to a supplier. Such segments in the chain do not need to test and keep extensive records. Those activities are properly accomplished by the supplier who converts the alfalfa into powder form and the end product manufacturer.

For the reasons described above, the economic impact of the CGMP's to Enrich International and other similar manufacturers is that the cost of the raw materials would escalate. Enrich International surveyed its suppliers and concluded that many do not follow those unnecessary aspects of the CGMP's, especially the requirements for laboratories, extensive record keeping, and heightened quality control requirements. However, please note that while these suppliers do not follow these CGMP standards, the quality of raw products they provide remains high. Enrich International annually receives over 2,000 shipments of ingredients. It tests every lot for E. coli and Salmonella. The rate of positive tests is a mere .05%, evidencing that Enrich's suppliers use high standards of cleanliness and quality control.

Response to FDA Request For Comments

Enrich International firmly believes that the Dietary Supplement Health Education Act of 1994("DSHEA") does not allow the FDA to impose GMP's for dietary supplements that are modeled after any GMP's other than those for foods. Furthermore, DSHEA prohibits the FDA from imposing "standards for which there is no current and generally available analytical methodology." Enrich International strongly opposes any effort by the FDA to circumvent these statutory proscriptions.

1. FDA REQUEST #1: Is there a need to develop specific defect action levels (DAL's) for dietary ingredients?
   RESPONSE: DAL's, if established, should be established according to industry practices and standards. However, they should be developed separately from the GMP's, as were the food DAL's.

2. FDA REQUEST #2: What are the appropriate testing requirements to provide positive identification of dietary ingredients, particularly plant materials?

   RESPONSE: Enrich International concurs that the analytical methodology available for identifying many plant materials is limited. The limitation is due to current methodologies of identifying active substances in herbs and then quantifying them. Many herbs and herbal products do not have known active substances. "Adequate testing" should therefore be limited to testing methodologies for plants with active substances. For plants without active ingredients, selection of a test should be a decision of the manufacturer.

3. FDA REQUEST #3: What standards should be met in certifying that a dietary ingredient or dietary supplement is not contaminated with filth; that it is free of harmful contaminants, pesticides residues, or other impurities; that it is microbiologically safe; and that it meets specified quality and identity standards.
   RESPONSE: This is an issue that should be limited to suppliers of dietary ingredients. A manufacturer of end products should be able to rely on a certification from the supplier, as is the case in the food GMP regulations. The validity of the certificate is adequately driven by market forces that deter falsification, including: the ability of an end product manufacturer to test the ingredients sold by the supplier; contractual remedies; and product liability exposure.

4. FDA REQUEST #4: Is there a need for CGMP's to include requirements to document that the procedures are followed on a day-to-day or continuing basis?
   RESPONSE: No. Doing so would unnecessarily raise the costs of production without producing measurable benefits. Manufacturer's should be allowed to establish Standard Operating Procedures ("SOP's) for compliance with GMP's.

5. FDA REQUEST #5: Should CGMP's require that reports of injuries or illnesses to a firm be evaluated by competent medical authorities to determine whether follow-up action is necessary to protect public health.

   RESPONSE: Requiring evaluation by medical authorities in GMP's goes beyond the scope of GMP's and would better be addressed elsewhere.

6. FDA REQUEST #6: Should CGMP's for dietary supplements require that manufacturers establish procedures to identify, evaluate, and respond to potential safety concerns with dietary ingredients.
   RESPONSE: The GMP's for foods do not have similar requirements. Such regulations would therefore violate the limitations of Section 9 of DSHEA.

7. FDA REQUEST #7: Are specific controls necessary for computer controlled or assisted operations.

RESPONSE: No. Testing, validation, and monitoring is normally conducted upon installation of the hardware/software by the vendors and monitored throughout the manufacturing processes. Adequate safeguards exist to control anomalies, especially final product inspections and testing.

8. FDA REQUEST #8: Would regulations for handling and manufacturing dietary ingredients and products be more effectively addressed by using principles of Hazard Analysis and Critical Control Points (HACCP)?
RESPONSE: The present mandatory applications of HACCP are for meats, seafood, and poultry. The environments these foods present are not similar to the environments for plants and herbal products. However, CGMP principles based on the principles of HACCP may provide a more flexible and less burdensome regulatory framework.

9. FDA REQUEST #9: Should CGMP's be broad to cover all segments of the dietary supplement industry, or should they address particular segments of the industry?
RESPONSE: The industry proposed CGMP's are too broad and would impose unnecessary procedures on different segments of the industry, especially the growers and brokers. As described above, the resulting impact would be unnecessary costs passed on to consumers. Enrich International strongly encourages the FDA to not impose the CGMP's on all segments. Furthermore, the FDA should consult with those segments of industry prior to establishing regulations.

Conclusion

Enrich International believes that the industry is self-regulating and that additional regulation is neither necessary nor desirable for the consumer. Government oversight is not necessary due to the extremely low incidents of adulterated or otherwise unsafe dietary supplements that enter the market. Additional regulation would provide an additional burden that would result in higher production costs with little increase in the level of safety to the consumer.

In the event that the FDA contemplates implementation of the CGMP's, it should be mindful that the CGMP's do not adequately address certain segments of the industry, particularly the growers and brokers. The CGMP's, if imposed on those segments of the industry, would unnecessarily raise the costs of raw material to end product manufacturers. The net result would be higher priced products with little or no additional assurances of safety to the consumer.

Respectfully yours,

Douglas M. Whitehead

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